SULODEXIDE (INN)

PRODUCT PROFILE
Brief Introduction

According to Martindale 34° Ed., Sulodexide is a heparinoid consisting of a mixture of low molecular weight heparin (Fast Moving Heparin, FMH) and Dermatan Sulfate (DS). Review of the 14th Annual Pharmacy Conference on Anticoagulation Therapy (1999) (1) also defines Sulodexide as a mixture of 80 % low molecular weight heparin and 20 % dermatan sulfate, total components of sulodexide being from porcine origin.

Use

Sulodexide (INN) is well known for the treatment of vascular pathologies with thrombotic risk, such as peripheral occlusive arterial disease, cardiovascular pathologies, etc. Due to its hypolipemiant activity (reducing triglycerides and cholesterol values in plasma), it is used also in the prophylaxis of myocardial re-infarction. Recently, novel application was found for Sulodexide, in the treatment of diabetic nephropathy in patients with both insulin and non-insulin dependent diabetes mellitus. Strong reduction in albumin excretion was obtained by using Sulodexide in such cases (2). The precise mechanism is not known but it may include restoration of the physiologic glomerular membrane anionic charge via enhanced synthesis and sulfation of heparin in renal vascular membranes, direct replenishment of renal heparin sulfate, inhibition of transforming growth factor β 1-mediated mesangial matrix overproduction, inhibition of mesangial cell hyperplasia, etc.

Production

Currently, Syntex S.A. is producing Sulodexide at kilo-lab scale.
### Specifications

**Appearance:** white or almost white powder  
**Solubility (5% soln.):** clear solution  
**pH (5% soln.):** 5.5 - 8.0  
**Loss on drying:** not more than 8.0%  
**Organic Sulphur:** 7.0 – 11.0% d.b.  
**Sulphate / carboxylic ratio:** $\geq 1.5$  
**Electrophoresis:**  
- CS: not more than 5%  
- DS: 15-25 %  
- FM: 75-85 %  
- SM: not more than 5%  
- OSCS: absent (NMR-H)  
**Heavy metals:** not more than 30 ppm  
**Anti-clotting activity:** not more than 70 IU/mg  
**Anti-Xa activity:** not less than 50 IU/mg  
**Residual solvents:**  
- methanol $\leq 500$ ppm  
- ethanol $\leq 1.5$ %  
- acetone $\leq 1000$ ppm  
**Total plate count:** not more than 1000 CFU/g  
**E. Coli:** absent /g  
**Salmonella:** absent / 10 g  
**S. Aureus:** absent /g  

### Note

Ideas and data previously mentioned must be understood just as guidelines in applications development and not as a recommendation of use against any patent.
Bibliographic Reference

1. [www.uspharmacist.com/ce/antico/lesson.html](http://www.uspharmacist.com/ce/antico/lesson.html)